

## Guidance for iPS Experiments Using Human Somatic Cells

The reprogramming of differentiated human somatic cells into a pluripotent state is increasingly performed by researchers. Regulatory requirements govern both the use of human somatic cells and their conversion to a pluripotent state. This guidance document addresses common questions that arise when grantees perform iPS experiments using human somatic cells and includes recommendations for SCRO approval letters or other assurances.

### Do iPS experiments using human somatic cells require IRB approval?

**YES:** Under [45 CFR 46](#) experiments using human somatic cells require IRB approval if:

- 1) The somatic cells are obtained from a living human donor, or
- 2) The investigator may readily ascertain the identity of the donor.

**NO:** If the investigator cannot readily ascertain the identity of the donor, then IRB approval is not required. The CIRM Medical and Ethical Standards (MES) regulations, title [17 California Code of Regulations, section 100080\(a\)\(3\)](#) includes additional requirements governing non-identifiable human somatic cells that may contain codes or links that would identify the specimen donor.

### Do iPS experiments using human somatic cells require SCRO approval?

**YES:** Under the CIRM Medical and Ethical Standards (MES) regulations, title [17 California Code of Regulations, section 100070\(c\)](#) research with the aim to derive or create cells in a pluripotent state (“covered stem cell line”) requires SCRO committee review and approval.

### Does the genetic modification of an established iPS or hESC line constitute a derivation of a “covered stem cell line”?

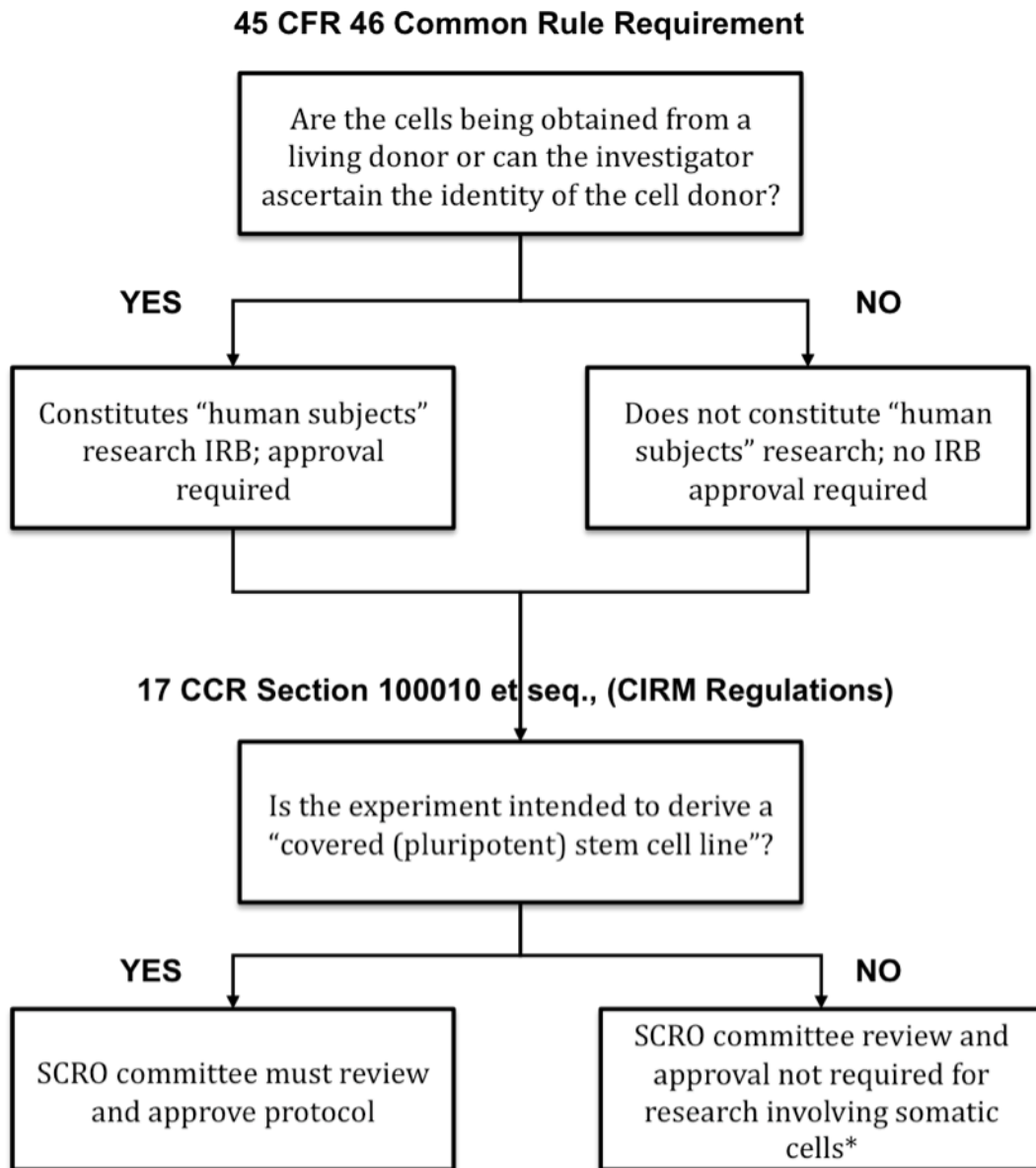
**NO:** All iPS or hESC (pluripotent) cell lines initially used in CIRM-funded research must be “acceptably derived.” Under the CIRM Medical and Ethical Standards (MES) regulations, title [17 California Code of Regulations, section 100090\(c\)](#) modification of an established, acceptably derived, cell line is not considered a new derivation.

### Recommended language for SCRO committee approval letters and assurances

The following statement is recommended for research involving the use of anonymous or “de-identified somatic cells:

*“The somatic cells have no associated identifiers, codes or links that would connect the donor’s identity to the investigator. If any codes or links exist to the identity of the donor, the codes or links are not readily ascertainable to the researcher.”*

## Decision Tree for iPS Experiments Using Human Somatic Cells in CIRM Funded Research



•One exception is the introduction of neural-progenitor cells into the brain of non-human animals; such experiments require SCRO approval.